

REMARKS/ARGUMENTS

In response to the Office Action mailed June 2, 2003, Applicants amend their application and request reconsideration in view of the amendments and the following remarks.

In this amendment, claim 4 is amended, no claims were added or cancelled so that claims 1-13 remain pending. No new matter has been introduced.

Claim 4 was rejected under 35 USC §112, second paragraph. Applicants have amended claim 4 in accordance with the Examiner's instructions; accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1, 4-11 and 13 were rejected as being unpatentable over US Patent No. 5,324,304 to Rasmussen in view of US Patent No. 4,832,055 to Palestrant. This rejection is respectfully traversed.

Rasmussen discloses an introduction catheter for a collapsible, self-expandable implant. Although stents are mentioned, the primary invention described relates to vascular filters. The introduction catheter comprises a flexible external guide sheath and a flexible internal filter catheter. The internal filter catheter is slidably displaceable inside the external-guide sheath. At its distal end, the flexible internal catheter is connected with a tubular end member. Slidably arranged inside the tubular end member is a filter retaining member serving to releasably retain the anchoring legs of the filter inside the tubular end member until the introduction catheter is positioned.

Palestrant discloses a mechanically locking blood clot filter. The filter comprises a central core wire and multiple peripheral wires that form the filter mesh. A first connector connects one end of each of the peripheral wires together and forms the nose of the filter. A second connector spaced a predetermined distance from the first connector comprises a tubular collar through which all of the wires pass. The portion of the wires between the two connectors form the filter mesh when deployed. Palestrant also discloses a delivery system for the filter. The delivery system comprises a delivery catheter, an outer catheter and a pusher catheter. The delivery system also comprises a moveable stop coupled to the pusher catheter for defining a fixed

spaced or distance between an infusion port and a portion of the stop. The stop is of a sufficient length to permit the delivery catheter and the outer catheter to be withdrawn to the extent that the peripheral wires forming the filter mesh are no longer encased by the delivery catheter while the leg assembly of the blood clot filter remain encased by the delivery catheter.

The present invention, as claimed in independent claim 1, is directed to a delivery apparatus for a self-expanding stent. The apparatus comprises an outer sheath and an inner shaft located coaxially and slidably within the outer sheath. The inner shaft also comprises a stop releasably affixed on an exterior surface thereof. The stop is configured to allow the outer sheath to move a predetermined distance, thereby enabling partial deployment of a self-expanding stent. The inner shaft further including at least two grooves disposed thereon.

The present invention, as claimed in independent claim 4, is directed to a stent delivery apparatus. The apparatus comprises an outer sheath comprising an elongated tubular member, an inner shaft located coaxially within the outer sheath, and a substantially cylindrical self-expanding stent located within the outer sheath. The inner shaft includes a stop releasably affixed on an exterior surface thereof adjacent to its proximal end. The stop is configured to allow the outer sheath to move a predetermined distance, thereby enabling partial deployment of a self-expanding stent. The inner shaft also including at least two grooves disposed thereon. The stent including at least two legs, each having a flange with one set in the grooves of the inner shaft.

The MPEP, in Section 706.02(j) sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on Applicants' disclosure. In re Vaack 947 F.2d, 488,20.USPQ2d 1438 (Fed.Cir. 1991). See MPEP §2143.03 for decisions pertinent to each of these criteria.

In making the rejection, the Examiner contends that Rasmussen discloses all of the claimed elements except for the stop. The Examiner further contends that Palestrant discloses a stop and that it would have been obvious to one of ordinary skill in the art to combine the teachings of the two references and thus have the claimed invention. Applicants respectfully disagree.

The claimed invention comprises a simple device comprising an outer sheath and an inner shaft located coaxially and slidably within the outer sheath. The inner shaft comprises a stop releasably affixed on an exterior surface of the inner shaft. The inner shaft also includes at least two grooves thereon. In claim 14, a self-expanding stent is claimed.

Rasmussen does not disclose an inner shaft disposed in an outer sheath and comprising a stop or at least the grooves therein. Rasmussen discloses a tubular end member having a filter-retaining member therein. Palestrant discloses a delivery system comprising a stop coupled to a pusher catheter where the pusher catheter comprises an infusion port. In addition, as set forth in Col. 15, lines 61-64, Palestrant discloses "a releasable stop 291 may be releasably coupled, as by a clip (not shown) to pusher catheter...". Palestrant does not disclose a stop that is removable by itself.

As one can see from a review of the cited references, neither reference, whether taken alone or in combination, discloses all of the claimed elements of the present invention.

"Although the suggestion to combine references may flow from the nature of the problem, defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness. Therefore...., the question is whether there is something in the prior art as a whole to suggest the desirability, and, thus, the obviousness of making the same invention."

Ecolochen, Inc. v. Southern California Edison Company, 227 F.3d, 1361, 1372 (Fed. Cir. 2000).

In other words, one cannot utilize the claimed invention as a template and then pick and choose from the prior art. Assuming arguendo that the combination of references teaches or suggests all of the claimed limitations, there is simply no motivation to combine the references. Rasmussen does not have a need for a stop.

Since there is no motivation to combine the references and the references fail to disclose all of the claimed limitations, there is no case of obviousness. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 2, 3, and 12 were rejected as being unpatentable over Rasmussen in view of Palestrant and further in view of US Patent No. 6,136,006 to Johnson et al. (Johnson). The rejection is respectfully traversed.

Johnson discloses a device for delivering a self-expanding stent. The device comprises an elongated exterior catheter, an interior catheter which is positioned in the lumen of the exterior catheter and a stent. The exterior catheter comprises a hub, and the interior catheter comprises a hub. An annular sleeve detent region is formed between the hubs and a sleeve surrounds the interior catheter and abuts to the hubs to prevent any movement of the interior catheter axially relative to the exterior catheter.

The combination of Rasmussen, Palestrant and Johnson fails to disclose all of the claimed elements of independent claims 1 and 4, and there is simply no motivation to combine the references as set forth above. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

A favorable action in the merits is earnestly solicited.

Respectfully submitted,



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